

In the instant Office Action, claims 12-15 are listed as pending and claims 12-15 are listed as rejected.

1-2. Obviousness under 35 U.S.C. 103(a)

The Examiner rejected claims 12-15 as being obvious over U.S. Patent No. 5,002,965 to Ramwell (hereinafter referred to as the "'965 patent").

A. The Examiner Has Not Made Out A Prima Facie Case Of Obviousness

The Examiner argues that the claims of the instant application are not patentably distinct from the `965 patent. The Examiner states that the `965 patent discloses "the applicant's preferred ginkgolides for use in preventing or reducing reperfusion injury in organ transplantation." The only difference between the teachings of the `965 patent and the instant application as noted by the Examiner is the instant application is directed to a pharmaceutical composition that is not discussed in the `965 patent. The Examiner opines that since the `965 patent discloses a therapeutic use for the preferred ginkgolides of the instant application, "one of ordinary skill in the art would have been motivated to employ the compounds in a pharmaceutical composition."

Applicant respectfully disagrees with the Examiner's conclusion that the `965 patent discloses a therapeutic use of the preferred ginkgolides of the instant application. As stated in Column I, Lines 39-52, the `965 patent discusses a

method of preserving tissue, particularly lung tissue intended for transplantation. It is important, according to '965 patent, that the ginkgolide, "be present in the organ after it has been transplanted." To accomplish this objective, the '965 patent states that the ginkgolide can be administered to the "organ donor". Given that most organ donors are deceased at the time that the organ is harvested, Applicant contends that the '965 patent is not directed to a therapeutic use of ginkgolide. Applicant is of the opinion that the ginkgolide used in the '965 patent is more analogous to an embalming fluid, than a medicament, and that one skilled in the art would not be motivated to use an embalming fluid in a pharmaceutical.

Applicant further contends that the Examiner's reliance on *In re Hack*, 114 USPQ 161 is misplaced. *Hack* applies to compositions, the long held rule of law, that the discovery of a new use of a product that is *structurally identical* to a known product will not support a new claim for the product. The Examiner admits in the instant action, that the composition claimed in the present application *differ* from the composition disclosed in the '965 patent. *Hack* as stated previously requires that the claimed product be *structurally identical* to the known product disclosed in the prior art. Applicant contends that merely having a component

in common, albeit the most important component, i.e., ginkgolide, does not render the compositions identical.

Applicant respectfully contends that the more appropriate standard to apply when considering the '965 patent would be the Doctrine of Slight Changes. *In re Wiggins*, 397 F.2d 356, 359, 158 CCPQ 199 (CCPA 1996). Similarity between two compounds, so long as the similarity does not amount to the exact identity of the structure, does not bar a patent. Claims 12-15 of the present application are directed to a pharmaceutical composition comprising "ginkgolide...together with at least one pharmaceutically acceptable carrier or excipient." The composition of the '965 patent does not contain a pharmaceutically acceptable carrier or excipient and is not structurally identical and can not, therefore, render the composition of the present application obvious.

Further, Applicant respectfully contends that the Examiner's statements misapprehend the standard of obviousness as applied in the genus / specie context. The Examiner's statements suggest that merely falling "within the scope" of prior art claims is sufficient grounds on which to base an obviousness rejection. However, the Court of Appeals for the Federal Circuit has rejected this approach, holding that

"[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious",

*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Rather, the CAFC has required that an obviousness rejection be supported by some suggestion in prior art to create the claimed invention, stating -

"[A] proper analysis under §103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed invention",

*In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (emphasis added).

The Examiner has failed to establish an element necessary to make out a *prima facie* case of obviousness, i.e., a showing of some suggestion or motivation in the prior art to combine prior art elements in order to arrive at the subject matter claimed in the instant application. Accordingly, the rejections under 35 U.S.C. §103(a) are obviated.

B. The Invention Of The Instant Application Possess Unexpected Advantages Over The Prior Art.

Assuming, *arguendo*, that the Examiner has made out a *prima facie* case of obviousness over the '965 patent, the rejection fails since the compounds claimed in the instant application possess unexpected advantages over those disclosed in the cited prior art.

A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds

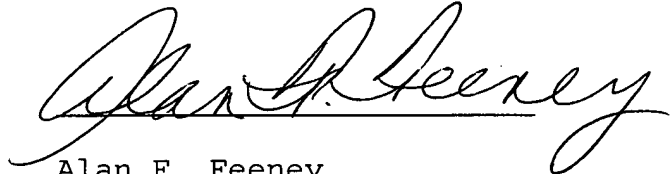
possess unexpectedly advantageous or superior properties. M.P.E.P. §2145 (Citing *In Re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).) In this regard Applicants direct the Examiner's attention to Tables I and II of the present application which evidences the ability of the compositions of the present application to decrease the levels of corticosterone in mammals. This highly desirable ability can not be determined from the '965 patent. Accordingly, the rejection under 35 U.S.C. §103(a) is obviated and should be withdrawn.

Based on the foregoing, Applicant respectfully submits that claims 12-15 are in condition for allowance. Prompt and favorable action is solicited.

Respectfully submitted,

Date: \_\_\_\_\_

9-24-2002



Alan F. Feeney  
Attorney for Applicants  
Reg. No. 43,609

Biomeasure Inc.  
27 Maple Street  
Milford, MA 01757-3650  
(508) 478-0144